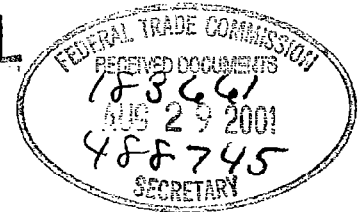


ORIGINAL



UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)	
)	
SCHERING-PLOUGH CORPORATION,)	
a corporation,)	
)	
UPSHER-SMITH LABORATORIES, INC.)	Docket No. 9297
a corporation, and)	
)	
AMERICAN HOME PRODUCTS CORPORATION,)	The Honorable
a corporation.)	D. Michael Chappell
)	Administrative Law Judge

RESPONSE OF THE FOOD AND DRUG ADMINISTRATION TO UPSHER-SMITH'S OPPOSITION TO THE FDA'S MOTION TO QUASH SUBPOENA

Upsher-Smith opposes FDA's motion to quash the subpoena, and seeks to distinguish the Commission's decision in Hoechst/Andrx (FTC Docket No. 9293). Despite Upsher-Smith's attempts, however, Hoechst/Andrx is clearly applicable. "There is *no basis* for holding that the Commission's Rules of Practice override FDA's own regulations governing document disclosure." Id. (emphasis added)

FDA's regulations, as set forth at 21 C.F.R. Part 20, promulgated to fulfill the requirements of the Freedom of Information Act, 5 U.S.C. § 552, prescribe the course Upsher-Smith must follow in order to pursue its request for the documents it seeks from FDA. These procedures apply regardless of whether FDA's regulations authorize or prohibit the release of the documents.

Moreover, should FDA deny Upsher-Smith's request for documents, the proper, and only, course for Upsher-Smith would be

to seek relief in a federal district court, not in this forum.

See 5 U.S.C. § 552(a)(4)(B).

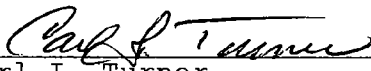
In sum, as this Court has already recognized, it has no authority to order FDA to act in violation of FDA's own regulations. Accordingly, FDA respectfully asks that the Court quash the subpoena duces tecum served upon it by Upsher-Smith.

Dated: August 28, 2001

Respectfully Submitted,

DANIEL TROY
CHIEF COUNSEL

By:


Carl I. Turner
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U.S. Food and Drug Administration
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Attorney for the United States
Food and Drug Administration

CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2001, I caused copies of the Response of the Food and Drug Administration to Upsher-Smith's Opposition to the FDA's Motion to Quash Subpoena and FDA's request for leave to file a response, to be served by Federal Express, postage prepaid, on:

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Karen G. Bokart
Federal Trade Commission, Rm. 3115
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

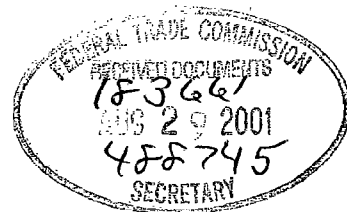
Cathy Hoffman
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Christopher M. Curran
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601 13th Street, N.W.
Suite 600 South
Washington, D.C. 20005


Carl I. Turner

August 28, 2001

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580



Dear Judge Chappell:

In accordance with the FTC Rules of Procedure, 16 C.F.R. § 3.22(c), the Food and Drug Administration respectfully requests leave to file a brief response to Upsher-Smith's Opposition To The FDA's Motion To Quash Subpoena. In its opposition, Upsher-Smith has raised a new issue regarding the availability of the documents it seeks from FDA, to which FDA would like to respond. Should our request be granted, I have enclosed a copy of our response. The original has been sent to the FTC Commissioner for filing should our request be granted, along with a copy of this letter. Copies have been served on the other counsel of record in this matter.

Sincerely,

Carl I. Turner
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Drug Administration
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Room 6-82
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enclosure